

IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF NEW YORK

PAULA K. FLY and
KENNETH FLY, her husband,

Plaintiffs,

Civil Action No.: 1:08-cv-3114

vs.

MERCK & CO., INC.,

Defendant.

COMPLAINT AND DEMAND FOR JURY TRIAL

Plaintiffs, PAULA K. FLY and KENNETH FLY, her husband, through their undersigned attorneys Levin, Papantonio et al., sue Defendant Merck & Company, Inc., and allege as follows:

I. JURISDICTION AND VENUE

1. This Court has jurisdiction pursuant to 28 U.S.C. §§1332, as complete diversity exists between Plaintiffs and Defendant. Plaintiffs are residents of the State of Mississippi, and Defendant is incorporated and has as its primary business in the State of New Jersey. The amount in controversy, exclusive of interest and costs, exceeds \$75,000.
2. Venue is proper within this district pursuant to Case Management Order No. 3, filed November 1, 2006, signed by John F. Keenan, allowing Fosamax-related cases to be

filed directly in the Southern District of New York.

II. PARTIES

3. Plaintiff PAULA K. FLY was born February 24, 1948. Plaintiff used FOSAMAX from approximately January 2002 until approximately April 2007. Plaintiff PAULA K. FLY was married to KENNETH FLY and they were residents of The State of Mississippi at all times material to this action.
4. Defendant is a corporation organized and existing under the laws of the State of New Jersey, with its principal place of business in New Jersey. The Defendant's registered office is at 820 Bear Tavern Road, City of West Trenton, Mercer County, New Jersey.
5. Defendant was at all relevant times authorized to conduct business in the State of Mississippi.
6. Defendant has regularly transacted business in the State of Mississippi and continues to do so.
7. At all relevant times Defendant, through its agents, servants, employees and apparent agents was the designer, manufacturer, marketer, distributor and seller of FOSAMAX, a bisphosphonate drug used primarily to mitigate or reverse the effects of osteoporosis.
8. Defendant, either directly or through its agents, apparent agents, servants or employees, at all relevant times, sold and distributed FOSAMAX in the State of Mississippi for the treatment of osteoporosis.

9. Defendant derives substantial revenue from pharmaceutical products used or consumed in the State of Mississippi.
10. Defendant expected, or should have expected, that its business activities could or would have consequences within the State of Mississippi.

III. SUMMARY OF THE CASE

11. Defendant, either directly or through its agents, apparent agents, servants or employees designed, manufactured, marketed, advertised, distributed and sold FOSAMAX for the treatment of osteoporosis, Paget's Disease, and other off-label uses.
12. As a result of the defective nature of FOSAMAX, persons who were prescribed and ingested FOSAMAX, including Plaintiff PAULA K. FLY, have suffered and may continue to suffer severe and permanent personal injuries to the jaw bone, including osteonecrosis of the jaw and other diagnoses of irreversible damage to the jaw.
13. Defendant concealed its knowledge of FOSAMAX's unreasonably dangerous risks from Plaintiff PAULA K. FLY, other consumers, and the medical community.
14. Defendant failed to conduct adequate and sufficient post-marketing surveillance of FOSAMAX after it began marketing, advertising, distributing, and selling the drug.
15. As a result of Defendant's actions and inaction, Plaintiff PAULA K. FLY was injured due to her ingestion of FOSAMAX, which has caused and will continue to cause Plaintiffs' various injuries and damages. Plaintiffs accordingly seek compensatory damages.

IV. FACTUAL BACKGROUND

16. At all relevant times Defendant was responsible for, or involved in, designing, manufacturing, marketing, advertising, distributing, and selling FOSAMAX.
17. In September 1995, the United States Food and Drug Administration ("FDA") approved Merck's compound alendronate, which is marketed by Merck as FOSAMAX, for various uses, including the treatment of osteoporosis and Paget's Disease.
18. FOSAMAX falls within a class of drugs known as bisphosphonates. Bisphosphonates are used for treating bone conditions such as osteoporosis and Paget's disease. Other drugs within this class such as Aredia and Zometa are also used as chemotherapy and as adjunct chemotherapy but are not indicated for use in non-cancerous conditions such as osteoporosis.
19. There are two classes of bisphosphonates: the N-containing (nitrogenous) and non-N-containing (non-nitrogenous) bisphosphonates. The nitrogenous bisphosphonates include the following: pamidronate (Aredia); ibandronate (Boniva); risedronate (Actonel); and alendronate (FOSAMAX). The non-nitrogenous bisphosphonates include the following: etridonate (Didronel); clodronate (Bonefos and Loron); and tiludronate (Skelid). Alendronate, like the others, contains a nitrogen atom, whereas etridonate, clodronate, and tiludronate do not. The PDR for FOSAMAX confirms that the molecule contains a nitrogen atom.

20. Throughout the 1990s and 2000s, medical articles and studies appeared reporting the frequent and common occurrence of osteonecrosis of the jaw with the use of nitrogenous bisphosphonates used for chemotherapy. As with its reported and acknowledged side effects concerning irritation, erosion, and inflammation of the upper gastrointestinal tract, Merck knew or should have known that FOSAMAX, as a nitrogenous bisphosphonate, shared an adverse event profile similar to that of the other drugs within this specific subclass of bisphosphonates (i.e., those containing nitrogen).
21. Merck knew and or should have known that bisphosphonates, including FOSAMAX, inhibit endothelial cell function. Similarly, Merck knew or should have known that bisphosphonates also inhibit vascularization of the affected area and induce ischemic changes specific to patients' mandibles (lower jaws) and maxillae (upper jaws) and that these ischemic changes appear to be cumulative in nature.
22. Merck also knew or should have known these factors combine to create a compromised vascular supply to the affected area. As a result, a minor injury or disease can turn into a non-healing wound. That in turn can progress to widespread necrosis (bone death) and osteomyelitis (inflammation of bone marrow).
23. Dentists are now being advised by state dental associations to refrain from using any invasive procedure (such as drilling a cavity) for any patient on FOSAMAX.
24. Once the osteonecrosis begins and becomes symptomatic, it is very difficult to treat and is not reversible.

25. Shortly after Defendant began selling FOSAMAX, reports of osteonecrosis of the jaw and other dental complications among users began surfacing, indicating that FOSAMAX shared the class effects of the other nitrogenous bisphosphonates. Despite this knowledge, Defendant failed to implement further study of the risk of osteonecrosis of the jaw relative to FOSAMAX. Rather than evaluating and verifying the safety of FOSAMAX with respect to osteonecrosis of the jaw, Defendant proposed further uses of FOSAMAX, such as FOSAMAX-D, and sought to extend the exclusivity period of FOSAMAX through 2018.
26. Osteonecrosis of the jaw is a serious medical event and can result in severe disability and death.
27. Since FOSAMAX was released, the FDA has received a number of reports of osteonecrosis of the jaw among users of FOSAMAX.
28. On August 25, 2004, the FDA posted its Office of Drug Safety ("ODS") Postmarketing Safety Review on bisphosphonates - - specifically pamidronate (Aredia), zoledronic acid (Zometa), risedronate (Actonel), and alendronate (FOSAMAX). This was an epidemiologic review of the FDA adverse events database conducted by the FDA's Division of Drug Risk Evaluation.
29. As a result of the FDA Review, the FDA observed that the risk of osteonecrosis of the jaw was not confined to bisphosphonates used for chemotherapy. The FDA's review indicated that osteonecrosis of the jaw was a class effect that specifically extended to the oral bisphosphonate FOSAMAX.

30. As a result, the FDA recommended and stated that the labeling for FOSAMAX should be amended by Merck to specifically warn about the risk of osteonecrosis of the jaw. Merck has refused to accede to the FDA's request and, to this day, still does not warn of the risk of osteonecrosis of the jaw in its FOSAMAX labeling.
31. Rather than warn patients, and despite Defendant's knowledge of an increased risk of osteonecrosis of the jaw in patients using FOSAMAX, Defendant continues to defend FOSAMAX and minimize unfavorable findings.
32. FOSAMAX is one of Defendant's top selling drugs, averaging more than \$3 billion a year in sales.
33. Consumers, including Plaintiff PAULA K. FLY, who have used FOSAMAX for treatment of osteoporosis, have several alternative safer products available to treat the conditions.
34. Defendant knew of the significant risk of dental and oral complications caused by ingestion of FOSAMAX, but Defendant did not adequately and sufficiently warn consumers, including Plaintiff PAULA K. FLY, or the medical community, of such risks.
35. As a direct result, Plaintiff PAULA K. FLY was prescribed FOSAMAX and has been permanently and severely injured, having suffered serious consequences from the ingestion of FOSAMAX. Plaintiff PAULA K. FLY requires and will in the future require ongoing medical care and treatment for the injuries she suffered as a result of taking FOSAMAX.

36. Plaintiff PAULA K. FLY has suffered mental anguish as a result of knowing the life-long complications she will suffer as a result of the injuries Plaintiff sustained from the use of FOSAMAX.
37. Plaintiff PAULA K. FLY was prescribed and began taking FOSAMAX in January 2002.
38. Plaintiff used FOSAMAX as prescribed and in a foreseeable manner.
39. As a direct and proximate result of using FOSAMAX, Plaintiff suffered severe personal injury to the jaw.
40. Plaintiff, as a direct and proximate result of using FOSAMAX, suffered severe mental and physical pain and has sustained permanent injuries and emotional distress.
41. Plaintiff used FOSAMAX which had been provided to her in a condition that was substantially the same as the condition in which it was manufactured and sold.
42. Plaintiff would not have used FOSAMAX had Defendant properly disclosed the risks associated with the drug. Alternatively, Plaintiff would have known the precursor events of osteonecrosis of the jaw and would have been able to avoid the clinical manifestation of the symptoms as they currently exist.
43. Defendant, through its affirmative misrepresentations and omissions, actively concealed from Plaintiff and her physicians the true and significant risks associated with taking FOSAMAX. The running of any applicable statute of limitations has been tolled by reason of Defendant's fraudulent concealment.

44. As a result of Defendant's actions, Plaintiff and her prescribing and treating physicians were unaware, and could not have reasonably known or have learned through reasonable diligence, that Plaintiff had been exposed to the risks identified in this complaint, and that those risks were the direct and proximate result of Defendant's acts, omissions, and misrepresentations.

V. COUNTS

COUNT I: NEGLIGENCE

45. Plaintiffs re-allege the above paragraphs as if fully set forth herein.
46. Defendant owed Plaintiff, PAULA K. FLY, other consumers, and physicians a duty to exercise reasonable care when designing, manufacturing, marketing, advertising, distributing, and selling FOSAMAX.
47. Defendant failed to exercise due care under the circumstances and therefore breached this duty by:
- a. failing to properly and thoroughly test FOSAMAX before releasing the drug to market;
 - b. failing to properly and thoroughly analyze the data resulting from the pre-marketing tests of FOSAMAX;
 - c. failing to conduct sufficient post-market testing and surveillance of FOSAMAX;
 - d. designing, manufacturing, marketing, advertising, distributing, and selling FOSAMAX to consumers, including Plaintiff, without an adequate warning of the significant and dangerous risks of FOSAMAX and without proper instructions to avoid the harm which

could foreseeably occur as a result of using the drug;

e. failing to exercise due care when advertising and promoting FOSAMAX; and

f. negligently continuing to manufacture, market, advertise, and distribute FOSAMAX after Defendant knew or should have known of its adverse effects.

48. As a direct and proximate consequence of Defendant's actions, omissions, and misrepresentations, Plaintiff PAULA K. FLY sustained significant and permanent injury of the jaw. In addition, Plaintiff required and will continue to require healthcare and services as a result of the injury suffered. Plaintiff has incurred and will continue to incur medical and related expenses as a result of her injury. Plaintiff has also suffered and will continue to suffer diminished capacity for the enjoyment of life, a diminished quality of life, increased risk of premature death, aggravation of preexisting conditions and activation of latent conditions, and other losses and damages. Plaintiff's direct medical losses and costs include care for hospitalization, physician care, monitoring, treatment, medications, and supplies. Plaintiff has suffered and will continue to suffer mental and physical pain as a result of her injuries.

49. Defendant's conduct as described above was committed with knowing, conscious, wanton, willful, and deliberate disregard for the value of human life and the rights and safety of consumers such as Plaintiff, thereby entitling Plaintiff to punitive damages so as to punish Defendant and deter it from similar conduct in the future.

50. Plaintiff PAULA K. FLY's spouse, KENNETH FLY, sustained a loss of consortium

as a result of the injuries and damages sustained by his wife incident to the use of FOSAMAX. His damages include, but are not limited to, a loss of society, companionship, services, support, and care. His losses are permanent and continuing in nature.

COUNT II: STRICT LIABILITY

51. Plaintiffs re-allege the above paragraphs as if fully set forth herein.
52. Defendant manufactured, sold, distributed, marketed, and/or supplied FOSAMAX in a defective and unreasonably dangerous condition to consumers, including Plaintiff PAULA K. FLY.
53. Defendant designed, manufactured, sold, distributed, supplied, marketed, and/or promoted FOSAMAX, which was expected to reach and did in fact reach consumers, including Plaintiff, without substantial change in the condition in which it was manufactured and sold by Defendant.
54. Plaintiff used FOSAMAX as prescribed and in a manner normally intended, recommended, promoted, and marketed by Defendant.
55. FOSAMAX failed to perform safely when used by ordinary consumers, including Plaintiff, including when it was used as intended and in a reasonably foreseeable manner.
56. FOSAMAX was defective in its design and was unreasonably dangerous in that its unforeseeable risks exceeded the benefits associated with its design or formulation.
57. FOSAMAX was defective in design or formulation in that it posed a greater

likelihood of injury than other similar medications and was more dangerous than an ordinary consumer could reasonably foresee or anticipate.

58. FOSAMAX was defective in its design and was unreasonably dangerous in that it neither bore nor was packaged with nor accompanied by warnings adequate to alert consumers, including Plaintiff, and or physicians, of the risks described herein, including, but not limited to, the risk of osteonecrosis of the jaw.
59. Although Defendant knew or should have known of the defective nature of FOSAMAX, it continued to design, manufacture, market, and sell FOSAMAX so as to maximize sales and profits at the expense of the public health and safety. By so acting, Defendant acted with conscious and deliberate disregard of the foreseeable harm caused by FOSAMAX.
60. Plaintiff and or her physician(s) could not, through the exercise of reasonable care, have discovered FOSAMAX's defects or perceived the dangers posed by the drug.
61. As a direct and proximate consequence of Defendant's actions, omissions, and misrepresentations, Plaintiff PAULA K. FLY sustained significant and permanent injury of the jaw. In addition, Plaintiff required and will continue to require healthcare and services as a result of the injury suffered. Plaintiff has incurred and will continue to incur medical and related expenses as a result of her injury. Plaintiff has also suffered and will continue to suffer diminished capacity for the enjoyment of life, a diminished quality of life, increased risk of premature death, aggravation of preexisting conditions and activation of latent conditions, and other losses and

damages. Plaintiff's direct medical losses and costs include care for hospitalization, physician care, monitoring, treatment, medications, and supplies. Plaintiff has suffered and will continue to suffer mental and physical pain as a result of her injuries.

62. Defendant's conduct as described above was committed with knowing, conscious, wanton, willful, and deliberate disregard for the value of human life and the rights and safety of consumers such as Plaintiff, thereby entitling Plaintiff to punitive damages so as to punish Defendant and deter it from similar conduct in the future.
63. Plaintiff PAULA K. FLY's spouse, KENNETH FLY, sustained a loss of consortium as a result of the injuries and damages sustained by his wife incident to the use of FOSAMAX. His damages include, but are not limited to, a loss of society, companionship, services, support, and care. His losses are permanent and continuing in nature.

COUNT III: BREACH OF EXPRESS WARRANTY

64. Plaintiffs re-allege the above paragraphs as if fully set forth herein.
65. Defendant expressly represented to Plaintiff PAULA K. FLY and other consumers and the medical community that FOSAMAX was safe and fit for its intended purposes, that it was of merchantable quality, that it did not produce any dangerous side effects, and that it was adequately tested.
66. FOSAMAX does not conform to Defendant's express representations because it is not safe, has numerous and serious side effects, and causes severe and permanent

injuries.

67. At all relevant times FOSAMAX did not perform as safely as an ordinary consumer would expect, when used as intended or in a reasonably foreseeable manner.
68. Plaintiff PAULA K. FLY, other consumers, and the medical community relied upon Defendant's express warranties.
69. As a direct and proximate consequence of Defendant's actions, omissions, and misrepresentations, Plaintiff PAULA K. FLY sustained significant and permanent injury of the jaw. In addition, Plaintiff required and will continue to require healthcare and services as a result of the injury suffered. Plaintiff has incurred and will continue to incur medical and related expenses as a result of her injury. Plaintiff has also suffered and will continue to suffer diminished capacity for the enjoyment of life, a diminished quality of life, increased risk of premature death, aggravation of preexisting conditions and activation of latent conditions, and other losses and damages. Plaintiff's direct medical losses and costs include care for hospitalization, physician care, monitoring, treatment, medications, and supplies. Plaintiff has suffered and will continue to suffer mental and physical pain as a result of her injuries.
70. Defendant's conduct as described above was committed with knowing, conscious, wanton, willful, and deliberate disregard for the value of human life and the rights and safety of consumers such as Plaintiff, thereby entitling Plaintiff to punitive damages so as to punish Defendant and deter it from similar conduct in the future.

71. Plaintiff PAULA K. FLY's spouse, KENNETH FLY, sustained a loss of consortium as a result of the injuries and damages sustained by his wife incident to the use of FOSAMAX. His damages include, but are not limited to, a loss of society, companionship, services, support, and care. His losses are permanent and continuing in nature.

COUNT IV: BREACH OF IMPLIED WARRANTY

72. Plaintiffs re-allege the above paragraphs as if fully set forth herein.
73. Defendant manufactured, distributed, advertised, promoted, and sold FOSAMAX.
74. At all relevant times, Defendant knew of the use for which FOSAMAX was intended and impliedly warranted the product to be of merchantable quality and safe and fit for such use.
75. Defendant was aware that consumers, including Plaintiff PAULA K. FLY, would use FOSAMAX for treatment of osteoporosis and for other purposes.
76. Plaintiff and the medical community reasonably relied upon the judgment and sensibility of Merck to sell FOSAMAX only if it was indeed of merchantable quality and safe and fit for its intended use.
77. Defendant breached its implied warranty to consumers, including Plaintiff; FOSAMAX was not of merchantable quality or safe and fit for its intended use.
78. Consumers, including Plaintiff, and the medical community, reasonably relied upon Defendant's implied warranty for FOSAMAX.

79. FOSAMAX reached consumers without substantial change in the condition in which it was manufactured and sold by Defendant.
80. As a direct and proximate consequence of Defendant's actions, omissions, and misrepresentations, Plaintiff PAULA K. FLY sustained significant and permanent injury of the jaw. In addition, Plaintiff required and will continue to require healthcare and services as a result of the injury suffered. Plaintiff has incurred and will continue to incur medical and related expenses as a result of her injury. Plaintiff has also suffered and will continue to suffer diminished capacity for the enjoyment of life, a diminished quality of life, increased risk of premature death, aggravation of preexisting conditions and activation of latent conditions, and other losses and damages. Plaintiff's direct medical losses and costs include care for hospitalization, physician care, monitoring, treatment, medications, and supplies. Plaintiff has suffered and will continue to suffer mental and physical pain as a result of her injuries.
81. Defendant's conduct as described above was committed with knowing, conscious, wanton, willful, and deliberate disregard for the value of human life and the rights and safety of consumers such as Plaintiff, thereby entitling Plaintiff to punitive damages so as to punish Defendant and deter it from similar conduct in the future.
82. Plaintiff PAULA K. FLY's spouse, KENNETH FLY, sustained a loss of consortium as a result of the injuries and damages sustained by his wife incident to the use of FOSAMAX. His damages include, but are not limited to, a loss of society,

companionship, services, support, and care. His losses are permanent and continuing in nature.

COUNT V: FRAUDULENT MISREPRESENTATION

83. Plaintiffs re-allege the above paragraphs as if fully set forth herein.
84. Defendant made fraudulent misrepresentations with respect to FOSAMAX in the following particulars:
 - a. Defendant represented through its labeling, advertising, marketing materials, detail persons, seminar presentations, publications, notice letters, and regulatory submissions that FOSAMAX had been tested and found to be safe and effective for the treatment of osteoporosis; and
 - b. Defendant represented that FOSAMAX was safer than other alternative medications.
85. Defendant knew that its representations were false, yet it willfully, wantonly, and recklessly disregarded its obligation to provide truthful representations regarding the safety and risk of FOSAMAX to consumers, including Plaintiff, and the medical community.
86. The representations were made by Defendant with the intent that doctors and patients, including Plaintiff, rely upon them.
87. Defendant's representations were made with the intent of defrauding and deceiving Plaintiff, other consumers, and the medical community to induce and encourage the sale of FOSAMAX.

88. Plaintiff PAULA K. FLY, Plaintiff's doctors, and others relied upon the representations.
89. Defendant's fraudulent representations evinced its callous, reckless, willful, and depraved indifference to the health, safety, and welfare of consumers, including Plaintiff.
90. As a direct and proximate consequence of Defendant's actions, omissions, and misrepresentations, Plaintiff PAULA K. FLY sustained significant and permanent injury of the jaw. In addition, Plaintiff required and will continue to require healthcare and services as a result of the injury suffered. Plaintiff has incurred and will continue to incur medical and related expenses as a result of her injury. Plaintiff has also suffered and will continue to suffer diminished capacity for the enjoyment of life, a diminished quality of life, increased risk of premature death, aggravation of preexisting conditions and activation of latent conditions, and other losses and damages. Plaintiff's direct medical losses and costs include care for hospitalization, physician care, monitoring, treatment, medications, and supplies. Plaintiff has suffered and will continue to suffer mental and physical pain as a result of her injuries.
91. Defendant's conduct as described above was committed with knowing, conscious, wanton, willful, and deliberate disregard for the value of human life and the rights and safety of consumers such as Plaintiff, thereby entitling Plaintiff to punitive damages so as to punish Defendant and deter it from similar conduct in the future.

92. Plaintiff PAULA K. FLY's spouse, JAMES A. KENNETH FLY, sustained a loss of consortium as a result of the injuries and damages sustained by his wife incident to the use of FOSAMAX. His damages include, but are not limited to, a loss of society, companionship, services, support, and care. His losses are permanent and continuing in nature.

COUNT VI: FRAUDULENT CONCEALMENT

93. Plaintiffs re-allege the above paragraphs as if fully set forth herein.
94. Defendant fraudulently concealed information with respect to FOSAMAX in the following particulars:
- a. Defendant represented through its labeling, advertising, marketing materials, detail persons, seminar presentations, publications, notice letters, and regulatory submissions that FOSAMAX was safe and fraudulently withheld and concealed information about the substantial risks of using FOSAMAX; and
 - b. Defendant represented that FOSAMAX was safer than other alternative medications and fraudulently concealed information which demonstrated that FOSAMAX was not safer than alternatives available on the market.
95. Defendant had sole access to material facts concerning the dangers and unreasonable risks of FOSAMAX.
96. The concealment of information by Defendant about the risks of FOSAMAX was intentional, and the representations made by Defendant were known by Defendant

to be false.

97. The concealment of information and the misrepresentations about FOSAMAX were made by Defendant with the intent that doctors and patients, including Plaintiff, rely upon them.
98. Plaintiff PAULA K. FLY, Plaintiff's doctors, and others relied upon the representations and were unaware of the substantial dental and oral risks of FOSAMAX which Defendant concealed from Plaintiff's doctors and Plaintiff.
99. As a direct and proximate consequence of Defendant's actions, omissions, and misrepresentations, Plaintiff PAULA K. FLY sustained significant and permanent injury of the jaw. In addition, Plaintiff required and will continue to require healthcare and services as a result of the injury suffered. Plaintiff has incurred and will continue to incur medical and related expenses as a result of her injury. Plaintiff has also suffered and will continue to suffer diminished capacity for the enjoyment of life, a diminished quality of life, increased risk of premature death, aggravation of preexisting conditions and activation of latent conditions, and other losses and damages. Plaintiff's direct medical losses and costs include care for hospitalization, physician care, monitoring, treatment, medications, and supplies. Plaintiff has suffered and will continue to suffer mental and physical pain as a result of her injuries.
100. Defendant's conduct as described above was committed with knowing, conscious, wanton, willful, and deliberate disregard for the value of human life and the rights

and safety of consumers such as Plaintiff, thereby entitling Plaintiff to punitive damages so as to punish Defendant and deter it from similar conduct in the future.

101. Plaintiff PAULA K. FLY 's husband, KENNETH FLY, sustained a loss of consortium as a result of the injuries and damages sustained by his wife incident to the use of FOSAMAX. His damages include, but are not limited to, a loss of society, companionship, services, support, and care. His losses are permanent and continuing in nature.

GLOBAL PRAYER FOR RELIEF

WHEREFORE, Plaintiffs demand judgment against Defendant, as follows:

- a. compensatory damages on each cause of action;
- b. punitive damages on each cause of action;
- c. reasonable attorneys' fees where recoverable;
- d. costs of this action; and
- e. such other additional and further relief as the Court may deem necessary, appropriate, and just.

VI. DEMAND FOR JURY TRIAL

Plaintiffs demand a trial by jury on all counts and issues so triable.

A handwritten signature in black ink, appearing to read 'Timothy M. O'Brien', is written over a horizontal line.

TIMOTHY M. O'BRIEN
MEGHAN M. TANS
LEVIN, PAPANTONIO, THOMAS, MITCHELL,
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JS 44C/SDNY
REV. 12/2005

CIVIL COVER SHEET

The JS-44 civil cover sheet and the information contained herein neither replace nor supplement the filing and service of pleadings or other papers as required by law, except as provided by local rules of court. This form, approved by the Judicial Conference of the United States in September 1974, is required for use of the Clerk of Court for the purpose of initiating the civil docket sheet.

PLAINTIFFS PAULA K. FLY AND KENNETH FLY, HER HUSBAND

DEFENDANTS MERCK & CO., INC.

ATTORNEYS (FIRM NAME, ADDRESS, AND TELEPHONE NUMBER)
LEVIN, PAPANTONIO, ET. AL., 316 S. BAYLEN STREET,
SUITE 600, PENSACOLA, FL 32591ATTORNEYS (IF KNOWN)
Meghan M. Tans, Timothy M. O'Brien

CAUSE OF ACTION (CITE THE U.S. CIVIL STATUTE UNDER WHICH YOU ARE FILING AND WRITE A BRIEF STATEMENT OF CAUSE)

28 U.S.C. 1332
PRODUCT LIABILITY - DEFECTIVE PHARMACEUTICAL (Fosamax)Has this or a similar case been previously filed in SDNY at any time? No ☐ Yes? ☒ Judge Previously Assigned KEENANIf yes, was this case Vol. ☐ Invol. ☐ Dismissed. No ☒ Yes ☐ If yes, give date _____ & Case No. _____

(PLACE AN [x] IN ONE BOX ONLY)

NATURE OF SUIT

		TORTS		FORFEITURE/PENALTY		BANKRUPTCY		OTHER STATUTES	
CONTRACT	PERSONAL INJURY	PERSONAL INJURY	[] 610 AGRICULTURE	[] 422 APPEAL	[] 400 STATE				
[] 110 INSURANCE	[] 310 AIRPLANE	[] 362 PERSONAL INJURY -	[] 620 FOOD & DRUG	[] 423 WITHDRAWAL	[] 410 ANTI-TRUST				
[] 120 MARINE	[] 315 AIRPLANE PRODUCT	LIABILITY	[] 625 DRUG RELATED	28 USC 158	[] 430 BANKS & BANKING				
[] 130 MILLER ACT	LIABILITY	[] 365 PERSONAL INJURY	SEIZURE OF	28 USC 157	[] 460 COMMERCE/CC				
[] 140 NEGOTIABLE	[] 320 ASSAULT, LIBEL &	PRODUCT LIABILITY	PROPERTY		[] 480 DEPORTATION				
INSTRUMENT	SLANDER	[] 368 ASBESTOS PERSONAL	[] 630 LIQUOR LAWS	PROPERTY RIGHTS	[] 470 RACKETEER INFLU-				
[] 150 RECOVERY OF	[] 330 FEDERAL	INJURY PRODUCT	[] 640 RR & TRUCK	[] 820 COPYRIGHTS	ENCED & CORRUPT				
OVERPAYMENT &	EMPLOYERS'	LIABILITY	[] 650 AIRLINE REGS	[] 830 PATENT	ORGANIZATION ACT				
ENFORCEMENT OF	LIABILITY	PERSONAL PROPERTY	[] 660 OCCUPATIONAL	[] 840 TRADEMARK	(RICO)				
JUDGMENT	[] 340 MARINE		[] 690 OTHER		[] 480 CONSUMER CREDIT				
[] 151 MEDICARE ACT	[] 345 MARINE PRODUCT	[] 370 OTHER FRAUD	LABOR	SOCIAL SECURITY	[] 490 CABLE/SATELLITE TV				
[] 152 RECOVERY OF	LIABILITY	[] 371 TRUTH IN LENDING	[] 710 FAIR LABOR	[] 851 MIA (1395FF)	[] 810 SELECTIVE SERVICE				
DEFAULTED	[] 350 MOTOR VEHICLE	[] 380 OTHER PERSONAL	STANDARDS ACT	[] 852 BLACK LUNG (923)	[] 850 SECURITIES/				
STUDENT LOANS	[] 355 MOTOR VEHICLE	PROPERTY DAMAGE	[] 720 LABOR/MGMT	[] 853 DIWC (405(g))	COMMODITIES/				
(EXCL VETERANS)	PRODUCT LIABILITY	PRODUCT LIABILITY	RELATIONS	[] 854 DIWW (405(g))	EXCHANGE				
[] 153 RECOVERY OF	[] 360 OTHER PERSONAL		[] 730 LABOR/MGMT	[] 864 SSID TITLE XVI	[] 875 CUSTOMER				
OVERPAYMENT OF	INJURY		REPORTING &	[] 865 RSI (405(g))	CHALLENGE				
VETERANS BENEFITS			DISCLOSURE ACT		12 USC 3410				
[] 160 STOCKHOLDERS SUITS			RAILWAY LABOR ACT	FEDERAL TAX SUITS	[] 891 AGRICULTURE ACTS				
[] 190 OTHER CONTRACT			[] 790 OTHER LABOR	[] 870 TAXES	[] 892 ECONOMIC				
[] 195 CONTRACT PRODUCT			LITIGATION	[] 871 IRS-THIRD PARTY	STABILIZATION ACT				
LIABILITY			[] 791 EMPL RET INC	20 USC 7609	MATTERS				
[] 196 FRANCHISE			SECURITY ACT		ENERGY				
	ACTIONS UNDER STATUTES	PRISONER PETITIONS			ALLOCATION ACT				
REAL PROPERTY	CIVIL RIGHTS				FREEDOM OF				
[] 210 LAND CONDEMNATION	[] 441 VOTING	[] 510 MOTIONS TO			INFORMATION ACT				
[] 220 FORECLOSURE	[] 442 EMPLOYMENT	VACATE SENTENCE			APPEAL OF FEE				
[] 230 RENT LEASE &	[] 443 HOUSING	28 USC 2255			DETERMINATION				
EJECTMENT	ACCOMMODATIONS	[] 530 HABEAS CORPUS			UNDER EQUAL ACCESS				
[] 240 TORTS TO LAND	[] 444 WELFARE	[] 535 DEATH PENALTY			TO JUSTICE				
[] 246 TORT PRODUCT	[] 445 AMERICANS WITH	[] 540 MANDAMUS & OTHER			[] 950 CONSTITUTIONALITY				
LIABILITY	DISABILITIES -	[] 550 CIVIL RIGHTS			OF STATE STATUTES				
[] 290 ALL OTHER	EMPLOYMENT	[] 555 PRISON CONDITION			[] 890 OTHER STATUTORY				
REAL PROPERTY	[] 446 AMERICANS WITH				ACTIONS				
	DISABILITIES -OTHER								
	[] 440 OTHER CIVIL RIGHTS								

Check if demanded in complaint:

CHECK IF THIS IS A CLASS ACTION
UNDER F.R.C.P. 23DO YOU CLAIM THIS CASE IS RELATED TO A CIVIL CASE NOW PENDING IN S.D.N.Y.?
IF SO, STATE:

DEMAND \$ _____ OTHER _____ JUDGE KEENAN DOCKET NUMBER 06-MDL 1789

Check YES only if demanded in complaint
JURY DEMAND: ☒ YES ☐ NO

NOTE: Please submit at the time of filing an explanation of why cases are deemed related.

(SEE REVERSE)

(PLACE AN x IN ONE BOX ONLY)

ORIGIN

- ☒ 1 Original Proceeding
 ☐ 2a. Removed from State Court
 ☐ 3 Remanded from Appellate Court
 ☐ 4 Reinstated or Reopened
 ☐ 5 Transferred from (Specify District)
 ☐ 6 Multidistrict Litigation
 ☐ 7 Appeal to District Judge from Magistrate Judge Judgment
- ☐ 2b. Removed from State Court
 AND at least one party is a pro se litigant

(PLACE AN x IN ONE BOX ONLY)

BASIS OF JURISDICTION

- ☐ 1 U.S. PLAINTIFF
 ☐ 2 U.S. DEFENDANT
 ☐ 3 FEDERAL QUESTION (U.S. NOT A PARTY)
 ☒ 4 DIVERSITY

IF DIVERSITY, INDICATE
CITIZENSHIP BELOW.
(28 USC 1332, 1441)

CITIZENSHIP OF PRINCIPAL PARTIES (FOR DIVERSITY CASES ONLY)

(Place an [X] in one box for Plaintiff and one box for Defendant)

	PTF	DEF		PTF	DEF		PTF	DEF
CITIZEN OF THIS STATE	[]	[]	CITIZEN OR SUBJECT OF A FOREIGN COUNTRY	[]	[]	INCORPORATED and PRINCIPAL PLACE OF BUSINESS IN ANOTHER STATE	[]	[]
CITIZEN OF ANOTHER STATE	[X]	[]	INCORPORATED or PRINCIPAL PLACE OF BUSINESS IN THIS STATE	[]	[]	FOREIGN NATION	[]	[]

PLAINTIFF(S) ADDRESS(ES) AND COUNTY(IES)

Paula K. Fly & Kenneth Fly
 1284 Highway 404
 Duck Hill, MS 38925

DEFENDANT(S) ADDRESS(ES) AND COUNTY(IES)

MERCK & CO., INC.
 ONE MERCK DRIVE
 P.O. BOX 100, WS3AB-05
 WHITEHOUSE STATION, NEW JERSEY, 08889-0100

DEFENDANT(S) ADDRESS UNKNOWN

REPRESENTATION IS HEREBY MADE THAT, AT THIS TIME, I HAVE BEEN UNABLE, WITH REASONABLE DILIGENCE, TO ASCERTAIN THE RESIDENCE ADDRESSES OF THE FOLLOWING DEFENDANTS:

Check one: THIS ACTION SHOULD BE ASSIGNED TO: ☐ WHITE PLAINS ☒ FOLEY SQUARE
 (DO NOT check either box if this a PRISONER PETITION.)

DATE 3/24/08 SIGNATURE OF ATTORNEY OF RECORD 

ADMITTED TO PRACTICE IN THIS DISTRICT
☐ NO
☒ YES (DATE ADMITTED Mo. 5 Yr. 2007)
 Attorney Bar Code # XXXXX

Magistrate Judge is to be designated by the Clerk of the Court.

Magistrate Judge _____ is so Designated.

J Michael McMahon, Clerk of Court by _____ Deputy Clerk, DATED _____

UNITED STATES DISTRICT COURT (NEW YORK SOUTHERN)

AO 440 (Rev. 10/93) Summons in a Civil Action - SDNY WEB 4/99

United States District Court

SOUTHERN

DISTRICT OF

NEW YORK

Paula K. Fly and Kenneth Fly, her husband

SUMMONS IN A CIVIL CASE

V.

CASE NUMBER:

MERCK & CO., INC.

TO: (Name and address of defendant)

MERCK & CO., INC.
C/O C T CORPORATION SYSTEM
111 EIGHTH AVENUE
NEW YORK, NEW YORK, 10011

YOU ARE HEREBY SUMMONED and required to serve upon PLAINTIFF'S ATTORNEY (name and address)

MEGHAN M. TANS
LEVIN, PAPANTONIO, THOMAS, MITCHELL, ECHSNER & PROCTOR, P.A.
316 S. BAYLEN STREET, SUITE 600
PENSACOLA, FL 32591

an answer to the complaint which is herewith served upon you, within _____ days after service of this summons upon you, exclusive of the day of service. If you fail to do so, judgment by default will be taken against you for the relief demanded in the complaint. You must also file your answer with the Clerk of this Court within a reasonable period of time after service.

CLERK

DATE

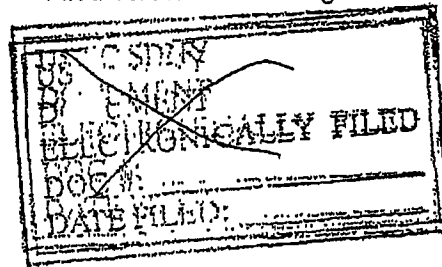
(BY) DEPUTY CLERK

AO 440 (Rev. 10/93) Summons In a Civil Action -SDNY WEB 4/99

RETURN OF SERVICE		
Service of the Summons and Complaint was made by me ¹	DATE	
NAME OF SERVER (PRINT)	TITLE	
<i>Check one box below to indicate appropriate method of service</i>		
<input type="checkbox"/> Served personally upon the defendant. Place where served: _____ _____		
<input type="checkbox"/> Left copies thereof at the defendant's dwelling house or usual place of abode with a person of suitable age and discretion then residing therein. Name of person with whom the summons and complaint were left: _____ _____		
<input type="checkbox"/> Returned unexecuted: _____ _____ _____		
<input type="checkbox"/> Other (specify): _____ _____ _____		
STATEMENT OF SERVICE FEES		
TRAVEL	SERVICES	TOTAL
DECLARATION OF SERVER		
<p style="text-align: center;">I declare under penalty of perjury under the laws of the United States of America that the foregoing information contained in the Return of Service and Statement of Service Fees is true and correct.</p> <div style="display: flex; justify-content: space-between;"> <div style="width: 45%;"> <p>Executed on _____ Date</p> </div> <div style="width: 45%;"> <p>_____ Signature of Server</p> <p>_____ Address of Server</p> </div> </div>		

(1) As to who may serve a summons see Rule 4 of the Federal Rules of Civil Procedure.

Case 1:06-md-01789-JFK-JCF Document 110 Filed 05/30/2007 Page 1 of 3



UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

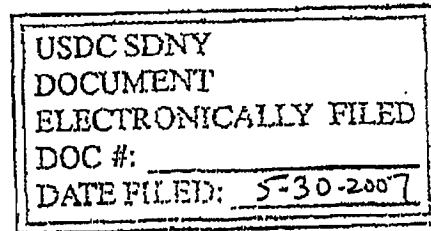
IN RE: Fosamax Products Liability
Litigation

1:06-md-1789 (JFK)

ORDER FOR ADMISSION
PRO HAC VICE

This Document Relates to: MDL-1789

Fredericka Allen v. Merck Case No.: 06-cv-9452
Bridget Arcemont v. Merck Case No.: 07-cv-3389
Virginia Bergeson v. Merck Case No.: 06-cv-9454
Shirley Boles v. Merck Case No.: 06-cv-9455
Sharon Bradford v. Merck Case No.: 07-cv-477
Winnie Braswell v. Merck Case No.: 1:07-cv-1413
Robertia Brodin v. Merck Case No.: 07-cv-3466
Brenda Carpenter v. Merck Case No.: 07-cv-3464
Sonja Daroff v. Merck Case No.: 07-cv-3462
Debra Flores v. Merck Case No.: 07-cv-02442
Sandra Hall v. Merck Case No.: 07-cv-3467
Porcia Hardy v. Merck Case No.: 07-cv-797
Carolyn Hester v. Merck Case No.: 06-cv-9450
Pamela Hines v. Merck Case No.: 07-cv-480
Rochelle Kenig v. Merck Case No.: 07-cv-00478
Anna Mervin v. Merck Case No.: 07-cv-3463
Junice Moe v. Merck Case No.: 07-cv-00479
James Nupier v. Merck Case No.: 06-cv-9451
Wilma Parslow v. Merck Case No.: 07-cv-3465
Tamara Porter v. Merck Case No.: 07-cv-790
Margaret Sixelove v. Merck Case No.: 07-cv-3459
Maxine Sklute v. Merck Case No.: 07-cv-3461
Edna Sykes v. Merck Case No.: 07-cv-1412
Kathleen Toelke v. Merck Case No.: 06-cv-7629
Reyna Vandercar v. Merck Case No.: 06-cv-11329
Nellie Wade v. Merck Case No.: 06-cv-9453
Carol Young v. Merck Case No.: 06-cv-0531
Bonnie Laughlin v. Merck Case No.: 07-cv-3827



Considering the Certificate of Good Standing submitted by counsel, IT IS

HEREBY ORDERED that:

Case 1:06-md-01789-JFK-JCF Document 110 Filed 05/30/2007 Page 2 of 3

Meghan M. Tans
Levin, Papantonio, Thomas, Mitchell, Echsner & Proctor, P.A.
316 S. Baylen Street, Suite 400
P.O. Box 12308 (32591)
Pensacola, FL 32502
Phone: (850) 435-7181
Facsimile: (850) 436-6181
Email: mtans@levinlaw.com

is admitted to practice pro hac vice as counsel for the plaintiffs in the above-referenced
MDL proceeding.

Signed this 30 day of May, 2007, at New York, New
York.


UNITED STATES DISTRICT COURT JUDGE

AO 136 (Rev. 9/98) Certificate of Good Standing

UNITED STATES DISTRICT COURT

MIDDLE DISTRICT OF FLORIDA

CERTIFICATE OF GOOD STANDING

I, Sheryl L. Loesch, Clerk of this Court,

certify that Meghan M. Tans, Bar # 00888745,

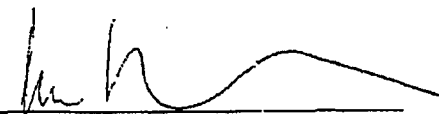
was duly admitted to practice in this Court on

April 22, 2005, and is in good standing

as a member of the Bar of this Court.

Dated at Jacksonville, Florida, on May 17, 2007.

SHERYL L. LOESCH
CLERK


DEPUTY CLERK